

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Goldstein, Steven et al.

Appln. No.: 10/734,096

Filed: December 11, 2003

For: RADICAL RETARDANT  
CRYOPRESERVATION  
SOLUTIONS

Attorney Docket No: 11930-135

Examiner: Barnhart, Lora  
Elizabeth

Art Unit: 1651

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, and more particularly in accordance with 37 C.F.R. §1.97(b), Applicants hereby cite the following reference(s):

### OTHER ART – NON PATENT LITERATURE DOCUMENTS

|   |
|---|
| Campbell, D.G. et al., "Sterilization of HIV by Gamma Irradiation. A Bone Allograft Model.", Int. Orthop, Vol. 18: No. 3, pp. 172-176, June 1994.   |
| Cooper, D.E. et al., "Contaminated Patellar Tendon Grafts: Incidence of Positive Cultures and Efficacy of an Antibiotic Solution Soak – an In Vitro Study", Arthroscopy Vol. 7, No. 3, pp. 272-274, 1991.   |
| Dichtelmuller, H. et al., "Validation of Virus Inactivation and Removal for the Manufacturing Procedure of Two Immunoglobulins and a 5% Serum Protein Solution Treated with Beta-Propiolactone", Biologicals, Vol. 21: No. 3, pp. 259-268. Sept 1993. |
| Erickson, G.A. et al., "Detection and Elimination of Adventitious Agents in Continuous Cell Lines", Dev Biol Stand, Vol. 70, pp. 59-66, 1989.   |
| Goertzen, M.J. et al., "Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants", Knee Surg Sports Traumatol Arthors, Vol. 4: No. 3, pp. 190, 1996.  |
| Keller, K.M., "Action of Hydrogen Peroxide on Degradation of DNA After Irradiation in Escherichia Coli", Int J Radiat Biol Relat Stud Phys Chem Med, Vol. 31: No. 5, pp. 407-413, May 1977.   |
| Lafferty, H.H. et al., "The Analysis of Decay Curves", Clin Sci Mol Med, Vol. 52: No. 1, pp. 97-101, Jan 1977.  |
| Lee, S.F. et al., "Induction Of c-Jun Protooncogene Expression By Hydrogen Peroxide Through Hydroxyl Radical Generation and p60 <sup>src</sup> Tyrosine Kinase Activation", Free Radic Biol. Med. Vol. 21, No. 4, pp. 437-448, 1996.                  |
| Lindsey, M.E. et al., "Quantitation of Hydroxyl Radical During Fenton Oxidation Following a Single Addition of Iron and Peroxide", Chemosphere, Vol. 41, No. 3, pp. 409-417, Aug. 2000.   |
| Liu, B. et al., "Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human Placenta Collagen", Chin Med Sci J. (China), Vol. 9: No. 2, pp. 100-103, June 1994.  |
| Marks, P.H. et al., "Reconstruction of the Cruciate Ligaments with Allogeneic Transplants, Techniques, Results and Perspectives", Orthopade, Vol. 22: No. 6, pp. 386-391  |
| Mello Filho, A.C. et al., "Cell Killing and DNA Damage by Hydrogen Peroxide are Mediated by Intracellular Iron", Biochem J, Vol. 218: No. 1, pp. 273-275, Feb 1984.   |

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| Mulford, D.J. et al., "Glutathione-S-Transferase-Mediated Methylthio Displacement and Turnover in the Metabolism of Pentachlorothioanisole by Rats", <i>Xenobiotica</i> , Vol. 21, No. 5, pp. 597-603, May, 1991.                 |
| Patchen, M.L. et al., "Glucan: Mechanisms Involved in its "Radioprotective" Effect", <i>J. Leukocyte Biol</i> , Vol. 42: No. 2, pp. 95-105, Aug 1987.   |
| Price, C.C. et al., "The Thermal Decomposition of Dimsyl Ion in Dimethyl Sulfoxide", <i>J. Org Chem</i> , Vol. 34: No. 9, pp. 2503-2506, Sept 1969.   |
| Repine, J.E. et al., "Hydrogen Peroxide Kills Staphylococcus Aureus by Reacting with Staphylococcal Iron to Form Hydroxyl Radical", <i>J Biol Chem</i> , Vol. 256: No. 14, pp. 7094-7096, July 1981.                              |
| Reszka, K.J. et al., <i>Free Radical Reactions Photosensitized by the Human Lens Component, Hynurenine: an EPR and Spin Trapping Investigation</i> , <i>Free Radic. Biol. Med.</i> Vol. 20, No. 1, pp. 23-24, 1996.               |
| Rimbach, G. et al., "Liver and Colon Oxidant Status in Growing Rats Fed Increasing Levels of Dietary Iron", <i>J. Trace Elem. Med. Biol.</i> Vol. 11, No. 2, pp. 99-104, June 1997.   |
| Schiller, J. et al., "Reactivity of Cartilage and Selected Carbohydrates with Hydroxyl Radicals: an NMR Study to Detect Degradation Products", <i>Free Radic Res</i> , Vol. 28: No. 2, pp. 215-228, Feb 1998.                     |
| Shen, B. et al., "Increased Resistance to Oxidative Stress in Transgenic Plants by Targeting Mannitol Biosynthesis to Chloroplasts", <i>Plant Physiol.</i> , Vol. 113, No. 4, pp. 1177-1183, April 1997.                          |
| Vasin, M.V., "Radioprotective Efficiency of Indraline With Local Gamma Radiation of the Skin", <i>Radiats Biol Radioecol (Russian)</i> , Vol. 38: No. 1, pp. 42-54, Jan-Feb 1998.   |
| "Virus Inactivation in Plasma Products", <i>Current Studies in Hematology and Blood Transfusion</i> , Vol. 56, pp.1-158.  |
| Weiss, H. et al., "Oxygen Depletion in Cells Irradiated at Ultra-High Dose-Rates and at Conventional Dose-Rates", <i>Int J. Radiat Biol., Relat Stud Phys Chem Med</i> , Vol. 26: No. 1, pp. 17-29, July 1974.                    |
| Willkommen, H. et al., "Theoretical Considerations on Viral Inactivation or Elimination", <i>Dev Biol Stand</i> , Vol. 81, pp. 109-116, 1993.   |
| Zhang, L. et al., "Effect of a Combined Gamma Irradiation and Parylene Plasma Treatment on the Hydrolytic Degradation of Synthetic Biodegradable Sutures", <i>J. Biomed Mater Res</i> , Vol. 27: No. 11, pp. 1425-1441, Nov 1993. |

Applicants are enclosing Form PTO-1449 (three sheets), along with a copy of each listed reference for which a copy is required under 37 C.F.R. §1.98(a)(2). As each of the listed references is in English, no further commentary is believed to be necessary, 37 C.F.R §1.98(a)(3). Applicants respectfully request the Examiner's consideration of the above reference(s) and entry thereof into the record of this application.

By submitting this Statement, Applicants are attempting to fully comply with the duty of candor and good faith mandated by 37 C.F.R. §1.56. As such, this Statement is not intended to constitute an admission that any of the enclosed references, or other information referred to therein, constitutes "prior art" or is otherwise "material to patentability," as that phrase is defined in 37 C.F.R. §1.56(a).



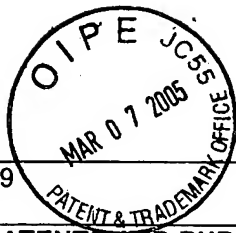
Applicants have calculated no fee to be due in connection with the filing of this Statement. However, the Director is authorized to charge any fee deficiency associated with the filing of this Statement to a deposit account, as authorized in the Transmittal accompanying this Statement.

Respectfully submitted,

3/2/05  
Date

Magdalena Cilella

Magdalena O. Cilella, Ph.D.  
Limited Recognition Certificate  
Submitted January 27, 2005  
Agent for Attorney of Record  
Customer No. 00757 – Brinks Hofer  
Gilson & Lioné



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| FORM PTO-1449   | SERIAL NO.<br>10/734,096         | CASE NO.<br>11930-135                  |
| LIST OF PATENTS AND PUBLICATIONS FOR<br>APPLICANT'S INFORMATION DISCLOSURE<br>STATEMENT | FILING DATE<br>December 11, 2003 | GROUP ART UNIT<br>1651                 |
| (use several sheets if necessary)   |                                  | APPLICANT(S): Goldstein, Steven et al. |

#### REFERENCE DESIGNATION

#### U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER<br><small>Number-Kind Code (if known)</small> | DATE | NAME | CLASS/<br>SUBCLASS | FILING<br>DATE |
|---------------------|--|------|------|--------------------|----------------|
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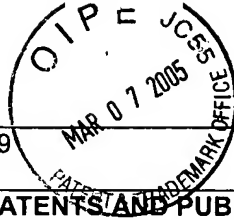
#### FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER<br><small>Number-Kind Code (if known)</small> | DATE | COUNTRY | CLASS/<br>SUBCLASS | TRANSLATION<br>YES OR NO |
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|---------------------|---|---|
|                     | B1  | Campbell, D.G. et al., "Sterilization of HIV by Gamma Irradiation. A Bone Allograft Model," Int. Orthop, Vol. 18: No. 3, pp. 172-176, June 1994.  |
|                     | B2  | Cooper, D.E. et al., "Contaminated Patellar Tendon Grafts: Incidence of Positive Cultures and Efficacy of an Antibiotic Solution Soak – an In Vitro Study", Arthroscopy Vol. 7, No. 3, pp. 272-274, 1991.   |
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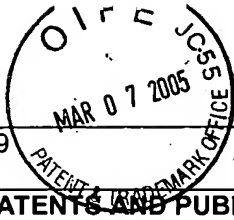


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|                     | B5  | Goertzen, M.J. et al., "Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants", Knee Surg Sports Traumatol Arthors, Vol. 4: No. 3, pp. 190, 1996.                             |
|                     | B6  | Keller, K.M., "Action of Hydrogen Peroxide on Degradation of DNA After Irradiation in Escherichia Coli", Int J Radiat Biol Relat Stud Phys Chem Med, Vol. 31: No. 5, pp. 407-413, May 1977.  |
|                     | B7  | Lafferty, H.H. et al., "The Analysis of Decay Curves", Clin Sci Mol Med, Vol. 52: No. 1, pp. 97-101, Jan 1977.   |
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|                     | B9  | Lindsey, M.E. et al., "Quantitation of Hydroxyl Radical During Fenton Oxidation Following a Single Addition of Iron and Peroxide", Chemosphere, Vol. 41, No. 3, pp. 409-417, Aug. 2000.  |
|                     | B10   | Liu, B. et al., "Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human Placenta Collagen", Chin Med Sci J. (China), Vol. 9: No. 2, pp. 100-103, June 1994.   |
|                     | B11   | Marks, P.H. et al., "Reconstruction of the Cruciate Ligaments with Allogeneic Transplants, Techniques, Results and Perspectives", Orthopade, Vol. 22: No. 6, pp. 386-391   |
|                     | B12   | Mello Filho, A.C. et al., "Cell Killing and DNA Damage by Hydrogen Peroxide are Mediated by Intracellular Iron", Biochem J, Vol. 218: No. 1, pp. 273-275, Feb 1984.  |
|                     | B13   | Mulford, D.J. et al., "Glutathione-S-Transferase-Mediated Methylthio Displacement and Turnover in the Metabolism of Pentachlorothioanisole by Rats", Xenobiotica, Vol. 21, No. 5, pp. 597-603, May, 1991.                            |
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|                     | B15   | Price, C.C. et al., "The Thermal Decomposition of Dimsyl Ion in Dimethyl Sulfoxide", J. Org Chem, Vol. 34: No. 9, pp. 2503-2506, Sept 1969.  |
|                     | B16   | Repine, J.E. et al., "Hydrogen Peroxide Kills Staphylococcus Aureus by Reacting with Staphylococcal Iron to Form Hydroxyl Radical", J Biol Chem, Vol. 256: No. 14, pp. 7094-7096, July 1981.   |
|                     | B17   | Reszka, K.J. et al., "Free Radical Reactions Photosensitized by the Human Lens Component, Hynurenine: an EPR and Spin Trapping Investigation", Free Radic. Biol. Med. Vol. 20, No. 1, pp. 23-24, 1996.                               |
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|                     | B19   | Schiller, J. et al., "Reactivity of Cartilage and Selected Carbohydrates with Hydroxyl Radicals: an NMR Study to Detect Degradation Products", Free Radic Res, Vol. 28: No. 2, pp. 215-228, Feb 1998.                                |
|                     | B20   | Shen, B. et al., "Increased Resistance to Oxidative Stress in Transgenic Plants by Targeting Mannitol Biosynthesis to Chloroplasts", Plant Physiol., Vol. 113, No. 4, pp. 1177-1183, April 1997.                                     |

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|                     | B21   | Vasin, M.V., "Radioprotective Efficiency of Indraline With Local Gamma Radiation of the Skin", Radiats Biol Radioecol (Russian), Vol. 38: No. 1, pp. 42-54, Jan-Feb 1998.   |
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